4164-01-P

This document is scheduled to be published in the Federal Register on 04/11/2022 and available online at **federalregister.gov/d/2022-07684**, and on **govinfo.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0552]

Safety and Performance Based Pathway Device-Specific Guidances; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of two final device-specific guidance documents for the Safety and Performance Based Pathway--specifically, "Surgical Sutures--Performance Criteria for Safety and Performance Based Pathway" and "Orthopedic Fracture Fixation Plates--Performance Criteria for Safety and Performance Based Pathway." The device-specific guidances identified in this notice were developed in accordance with the finalized guidance entitled "Safety and Performance Based Pathway."

DATES: The announcement of the guidances is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-D-0552 for "Surgical Sutures--Performance Criteria for Safety and Performance Based Pathway" or "Orthopedic Fracture Fixation Plates--Performance Criteria for Safety and Performance Based Pathway." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance documents are available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidances. Submit written requests for a single hard copy of the guidance document entitled "Surgical Sutures--Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff" or the guidance document entitled "Orthopedic Fracture Fixation Plates--Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993-0002, 301-796-4908.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of two final device-specific guidance documents for the Safety and Performance Based Pathway--specifically, "Surgical Sutures--Performance Criteria for Safety and Performance Based Pathway" and "Orthopedic Fracture Fixation Plates--Performance Criteria for Safety and Performance Based Pathway." These device-specific guidance documents provide performance criteria for premarket notification (510(k)) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled "Safety and Performance Based Pathway."[1] As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter of a surgical suture or orthopedic fracture fixation plate device could satisfy the requirement to compare its device with a legally

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.

marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the relevant above-listed guidance rather than using direct predicate comparison testing for some of the performance characteristics.

These guidances are being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that these guidance documents present less burdensome policies that are consistent with public health. Although these guidances are being implemented immediately, FDA will consider all comments received and revise the guidance documents as appropriate.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the current thinking of FDA on "Surgical Sutures--Performance Criteria for Safety and Performance Based Pathway" and "Orthopedic Fracture Fixation Plates--Performance Criteria for Safety and Performance Based Pathway." They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. These guidance documents are also available at https://www.regulations.gov or https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Surgical Sutures--Performance Criteria for Safety and Performance Based Pathway" or "Orthopedic Fracture Fixation Plates--Performance Criteria for Safety and Performance Based Pathway" may send an

email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 20002 for "Surgical Sutures--Performance Criteria for Safety and Performance Based Pathway" or document number 19044 for "Orthopedic Fracture Fixation Plates--Performance Criteria for Safety and Performance Based Pathway" to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulation and guidance have been approved by OMB as listed in the following table:

21 CFR Part; Guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"	Q-submissions; pre-submissions	0910-0756

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-07684 Filed: 4/8/2022 8:45 am; Publication Date: 4/11/2022]